K052411

SEP 2 1 2005

Steinhart Medizinsysteme GmbH

510(k) Summary

Summary of functions of the device and its major components provided as part of the Device Description for HIPAX Medical Imaging Software, according to the Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, 2000.

Date:	July 27th 2005
Company Name:	Steinhart Medizinsysteme GmbH
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Device Trade Name:	HIPAX Medical Imaging Software
Device Common Name:	Picture Archiving Communications System (PACS)
Product Code:	LLZ
Regulation No.	892.2050
Device Classification:	Class II
Predicate Devices:	Radworks Medical Imaging Software (K962699) eFilm Workstation (K012211)

Device Description

The Hipax Medical Imaging Software is an autonomous software and involves no hardware with the exception of a dongle for copy protection. It is running under Microsoft Windows 2000/XP operating system on any hardware platform meeting the minimum system requirements and supporting the Windows 2000/XP operating system.

The Hipax Medical Imaging Software has an open system architecture consisting of a basic module for image processing and viewing, and a number of modules for image acquisition, storage and communication to be added as an option.

The functions of the Hipax Medical Imaging Software correspond to the features described for the Predicate Devices: Displaying any medical image, for example, from CT, MRI, CR, US, endoscopy, gastroscopy, and others. The Hipax Medical Imaging Software offers features routinely used by radiologists and other medical specialists (e.g. window leveling, ROIs, edge enhancement, zooming, magnifying glass, cine-loop, measurement, writing and marking, histogram etc.). Multiplanar Reconstruction is available as an option.
Like the Predicate Devices, the Radworks Medical Imaging Software or the eFilm Workstation, the Hipax Medical Imaging Software offers functions for image acquisition from video sources (Video Module) digitizers (X-ray Digitizing Module), or CR systems (CR-Connection Module). Within a network DICOM worklists can be received and images can be sent and received using the DICOM protocol. Image exchange between two remote Hipax Workstations or other Hipax programs via phone lines, broadband, satellite, etc. can be carried out using the Hipax DICOM Communication module, which is also part of the Radworks Medical Imaging Software. The DICOM Email module is available to transmit images as Emails. Images can be compressed and encrypted. The DICOM Print Module supports DICOM 3.0 printing. Using the Patient-CD module images can be written on CD to be handed out to the patient. The Lokal Archive module is available for image storage

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on digital media, e.g. DVD. To burn CDs or DVDs automatically, a CD/DVD robot can be connected.

Intended Use

The Hipax Medical Imaging Software is intended to be used for medical image processing and communication. Medical Images (single images, series or sequences) and corresponding patient data can be received from various sources, e.g. from CR, CT, MRI, US, R/F units, secondary capture devices as scanners, video sources, etc. Images can be administrated, displayed, transmitted and stored on the local disk of a workstation as well as on distributed locations across a network, or on optical or digital media, e.g. CD or DVD. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Functions to be carried out using the Hipax Medical Imaging Software are, for example, but not limited to, adjustment of window leveling, defining region of interest, image stacking, MPR, rotation, zoom, measurements. The Hipax Medical Imaging Software can be integrated into a patient administration system.

Users of the Hipax Medical Imaging Software are typically trained medical professionals, for example, radiologists, orthopedists, clinicians, technologists, and others.

Technological Characteristics

The Hipax Medical Imaging Software is a stand-alone software, like the Predicate Devices. It can be used on more than one hardware platform. As long as minimum hardware requirements are met, the user is free to choose his/her own hardware platform.

The Hipax Medical Imaging Software as well as the Predicate Devices allow digital image processing and measurement capability.

The Hipax Medical Imaging Software nor contacts the patient, neither controls any life-sustaining devices. Physicians providing the adequate expert knowledge for competent human intervention interpret images and information being displayed and/or printed.

Testing

The Hipax Medical Imaging Software is tested according to the specifications that are documented in an own description (Description of the software test procedures) and the corresponding Softwaretest forms. Testing is an integral part of the software development process of Steinhart Medizinsysteme GmbH (see documents in G 2 and G 4).

Conclusion

The Hipax Medical Imaging Software is a medical device. It has the same indications for use and target population as the legally marketed Predicate Devices.

The Hipax Medical Imaging Software has the same technological characteristics as the Predicate Devices.

This premarket notification describes the characteristics of the Hipax Medical Imaging Software in sufficient detail to assure substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Steinhart Medizinsysteme GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV America, Inc.
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K052411
Trade/Device Name: Hipax Medical Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 22, 2005
Received: August 29, 2005

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052411

Device Name: Hipax Medical Imaging Software

Indications for Use:

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Prescription Use × (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052411